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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA
WESTERN DIVISION

FULFILLIUM, INC., Plaintiff, v. RESHAPE MEDICAL, LLC and RESHAPE LIFESCIENCES, INC. Defendants.	Case No. 8:18-cv-01265-RGK-PLA **PLAINTIFF'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT ON THE ISSUE OF INFRINGEMENT** Date: August 12, 2019 Time: 10 a.m. Place: Roybal Building, Courtroom 780 Judge: Hon R. Gary Klausner

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Plaintiff Fulfillium, Inc. respectfully submits this memorandum in support of its Motion for Partial Summary Judgment of Infringement. Fulfillium seeks summary judgment that Defendants ReShape Medical, LLC and ReShape Lifesciences, Inc. have infringed independent claim 1 of each of U.S. Patent Nos. 9,445,930 (the " " '930 patent"); 9,808,367 (the " '367 patent"); and 9,456,915 (the " '915 patent") (collectively the "Patents-in-Suit") as well as claims 5, 6, and 11 of the '930 patent and claim 7 of the '367 patent. Fulfillium's Motion is supported by a L.R. 56-1 Statement of Uncontroverted Facts and Conclusions of Law ("SUF") as well as the Declarations of W. Cook Alciati and Dr. Sunil Bhoyrul. Dr. Bhoyrul is a bariatric surgeon who is skilled in the pertinent art.

INTRODUCTION

Defendants did not serve a substantive noninfringement position until after the close of discovery. To avoid motion practice, Fulfillium agreed to accept service of those contentions. When Fulfillium finally discovered Defendants noninfringement positions, Fulfillium learned that they were all premised on Defendants unsupported attempt to manufacture a noninfringement defense by reading limitations into the claims that are not recited in the claims. There is no basis in the intrinsic record or otherwise for Defendants' proposed constructions.

Defendants are forced to contrive limiting claim constructions because they infringe the Patents-in-Suit when those patents are properly understood according to their plain and ordinary meaning. Indeed, Defendants largely admitted that all elements of the claims in the Patents-in-Suit are literally present in the accused device during their Rule 30(b)(6) deposition. Defendants are bound by those admissions. No reasonable jury could find that the accused devices do not include each and every element of claim 1 of the each of the Patents-in-Suit. Summary judgment of infringement is appropriate in this case.

STATEMENT OF FACTS

A. The Patents-in-Suit

The Patents-in-Suit are all directed to a gastric balloon device. Bhoyrul Decl. ¶ 14. A gastric balloon device is a non-surgical treatment for obesity which is inserted endoscopically into the patient's stomach. *Id.* Once the device is within the patient's stomach, it is inflated with a fluid, such as saline. *Id.* The inflated device occupies space in the stomach, leading to a sense of satiety. *Id.* With the patient feeling satiated, the patient will consume less calories and lose weight. *Id.*

The specification explains that "the present disclosure provides improved gastric balloons and methods for their deployment and use." *See, e.g.,* '915 patent, Col. 8, ll. 59-60. The specification discloses various embodiments of a gastric balloon structure. One such embodiment discloses a dual balloon structure in which the balloons are connected by a flexible spine. That embodiment is shown in Fig. 15F (right). As can be seen, the device includes two balloons 1540 and 1542 that are connected with a flexible central spine. This design is substantially similar to the design of a prototype device Fulfillium developed in the early 2000s (shown to the right). In the potential commercial embodiment of Fulfillium's gastric balloon technology, the device includes two balloons connected by a flexible spine that allows the gastric balloon structure to conform to the shape of the gastric cavity.

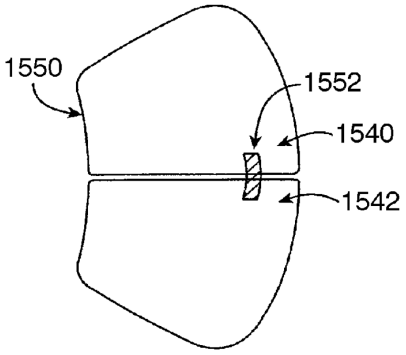
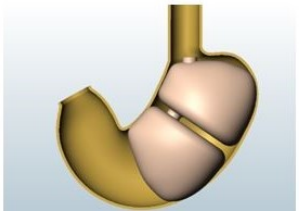


FIG. 15F

Current Thoughts on Product Design

Alternative designs.



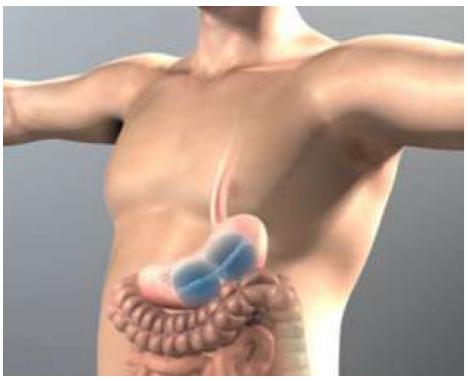
Basic features
- Follows our patent principles
- >1 balloons
- Intermediate stage of "holding" food

Others…

Independent claim 1 of each of the Patents-in-Suit is generally directed to a gastric balloon structure including multiple balloons connected by a flexible central spine with the structure conforming to a curved shape in the patient's stomach. The dual balloon design enhances the safety of the device as well as patient comfort.

B. Accused Products

Defendants sold a gastric balloon device between 2016 and 2018 that infringed the Patents-in-Suit. SUF, ¶ 2. The device has been called two different names, but there is no material difference between the two differently named devices as it relates to this litigation. *Id.* ¶ 3. The infringing devices will be referred to herein as the "ReShape Balloon." The structure of the ReShape Balloon is substantially similar to the embodiments of the Fulfillium balloon depicted above. An image from the ReShape Balloon Instructions for Use is reproduced to the right. The ReShape Balloon "is a temporary implant designed to facilitate weight loss by occupying space in the stomach." *Id.* ¶ 13. "The device's flexible dual balloon design is intended to improve patient comfort while reducing the risk of device migration into the intestine." *Id.* ¶ 59. In particular, the two interconnected balloons are designed to better fit the natural contour of the stomach, thereby increasing the level of patient comfort. *Id.* ¶ 57.



C. The Parties

Dr. Richard Chen founded Fulfillium in 2004 to commercialize his ideas concerning an improved gastric balloon. SUF, ¶ 4. In 2005, Dr. Chen embarked on an effort to seek funding for Fulfillium from venture capital firms, including SV Lifesciences (the original investor in ReShape). *Id.* ¶¶ 60, 61.

In 2005, Dr. Chen sent to SV a copy of analysis conducted by Fulfillium that "practically outline[d] the design specs for the next generation of the product, form[ed] the basis for Fulfillium's IP, and represent[ed] the fruits of [Dr. Chen's] labors over the past years." SUF, ¶ 48. Upon providing such information, Dr. Chen stated: "I trust that they will be kept confidential and, in the event there is no deal, destroyed." *Id*.

SV intended to partner with Intersect Partners LLC, which was managed by one their venture partners, George Wallace. *Id*. ¶¶ 62, 63. [redacted] *Id*. Fulfillium, SV, and Intersect were unable to agree upon terms at which point SV and Intersect decided to fund and form Abdominis, Inc. with Mr. Wallace as the Chief Executive Officer. *Id*. ¶¶ 64, 65.

In connection with the funding of Abdominis, [redacted] *Id*. ¶ 65. [redacted] *Id*. ¶¶ 65-67. [redacted] *Id*. ¶ 67.

Plainly put, when SV and Intersect could not reach a deal with Fulfillium, they decided to launch their own gastric balloon company all while keeping Dr. Chen and Fulfillium in the dark on their plan to launch a competitive company based on the confidential information disclosed by Fulfillium. *See, e.g.,* ¶¶ 68-72. [redacted] *Id*.

In the years following the formation of Abdominis, the name was changed to ReShape Medical. *Id*. ¶ 73. At a Board of directors meeting in 2009, ReShape discussed [redacted] *Id*. ¶ 74. [redacted]

[redacted] In fact, Defendants admitted during the Rule 30(b)(6) [redacted] SUF, ¶ 75. Indeed, [redacted] SUF, ¶¶ 75-76. Despite that intimate knowledge of Fulfillium's intellectual property Defendants charged ahead to commercialize Fulfillium's gastric balloon technology.

LEGAL STANDARDS

Summary judgment is appropriate when there is no genuine issue of material fact for trial. Fed. R. Civ. P. 56(c). "By its very terms, this standard provides that the mere existence of *some* alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no *genuine* issue of *material* fact." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 247-48 (1986) (original emphasis).

"An infringement issue is properly decided upon summary judgment when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device either literally or under the doctrine of equivalents." *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1339 (Fed. Cir. 2001). "Where the only dispute is about the proper claim construction, summary judgment is appropriate." *Bragel Int'l, Inc. v. Kohls's Dept. Stores, Inc.*, No. 2:17-cv-07414-RGK-SS, 2019 WL 1425058, at *2 (C.D. Cal. Jan. 25, 2019).

"A determination of infringement requires a two-step analysis." *Gart*, 254 F.3d at 1339. First, the claim must be construed. *Id*. Second, "the claim as properly construed must be compared to the accused device or process." *Id*. "In order for a court to find infringement, the plaintiff must show for the presence of every … limitation or its substantial equivalent in the accused device." *Id*. Claim

construction is an issue of law, and infringement is a question of fact." *Id*.

ARGUMENT

A. The claim terms of the Patents-in-Suit are all properly understood according to their plain and ordinary meaning.

"It is the claims that define the metes and bounds of the patentee's invention." *Thorner v. Sony Computer Entmt.*, 669 F.3d 1362, 1367 (Fed. Cir. 2012). "The patentee is free to choose a broad term and expect to obtain the full scope of its plain and ordinary meaning unless the patentee explicitly redefines the term or disavows its full scope." *Id.* A patentee can explicitly redefine a term through lexicography, which requires a patentee to "clearly set forth a definition of the disputed claim term other than its plain and ordinary meaning." *Id*. at 1365. "It is not enough for a patentee to simply disclose a single embodiment or use a word in the same manner in all embodiments, the patentee must clearly express an intent to define the term." *Id*. A patentee can also limit claim scope through disavowal. Like lexicography, "the standard for disavowal is similarly exacting." *Id*. "To constitute disclaimer, there must be a clear and unmistakable disclaimer." *Id*. at 1366-67.

Despite relying on claim constructions that depart from the ordinary meaning of the claim terms, Defendants did not offer any proposed constructions until the last day of discovery. SUF, ¶ 80. Defendants thereafter supplemented their response after the close of discovery on July 2, 2019. *Id*. ¶ 81. When Defendants finally did take a position, they revealed claim constructions that would rewrite the claims in various ways that are not supported by the facts or law. Defendants cite to no clear and unmistakable disclaimer that would support their narrowing constructions. Absent such disclaimer, the claim terms are presumed to have their ordinary meaning. In this case, the words of the claims are easily understood by lawyers, judges, and jurors alike without the need for specific construction. *Phillips*

v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc).

B. Defendants infringe independent claim 1 of each of the Patents-in-Suit.

1. Defendants infringe the '930 Patent

a. Preamble

The preamble of claim 1 of the '930 patent recites: "An obesity treatment device for deploying in a stomach of patient, comprising." SUF, ¶ 8. To the extent the preamble is limiting, it is met because the ReShape Balloon is a device used to treat obesity that is deployed in the stomach of the patient. SUF, ¶ 13; Bhoyrul Dec., ¶¶ 23-24.

b. First element

The first element of claim 1 of the '930 patent recites "a plurality of adjacent, spaced-apart inflatable space-filling compartments, wherein each compartment of the plurality of inflatable space-filling compartments has a respective inflated state volume that is maintained during treatment of the patient." SUF, ¶ 8. A POSITA would understand the words of this claim limitation according to their plain and ordinary meaning without the need for further construction. Bhoyrul Dec., ¶ 26.

A POSITA would recognize this claim limitation as literally present in the ReShape Balloon. *Id.*, ¶¶ 27-34. The ReShape Balloon includes "two independently inflated, non-communicating, silicone balloons tethered to a central silicone shaft." SUF, ¶ 14; Bhoyrul Dec., ¶ 28. A POSITA would understand that the two balloons, which are located next to each and inflated after the device is implanted in the stomach, to constitute "a plurality of adjacent, spaced-apart inflatable filling compartments." Bhoyrul Dec., ¶ 29.

Each of the two balloons of the ReShape Balloon is inflated to a specified volume. SUF, ¶ 15. Once inflated, that volume is maintained during treatment of patient by, for example, the valve system discussed below. SUF, ¶ 15; Bhoyrul

Dec., ¶¶ 30-33. A POSITA would understand this to meet the requirement that "each compartment of the plurality of inflatable space-filling compartments has a respective inflated state volume that is maintained during treatment of the patient." Bhoyrul Dec., ¶¶ 30-34.

c. Second element

The second element of claim 1 of the '930 patent recites: "a valve system for introducing a fluid into each compartment of the plurality of inflatable space-filling compartments and for retaining, upon inflation, fluid in the plurality inflatable space-filling compartments, wherein" SUF, ¶ 8. A POSITA would understand the words of this claim limitation according to their plain and ordinary meaning without the need for further construction. Bhoyrul Dec., ¶ 36.

A POSITA would recognize this claim limitation as literally present in the ReShape Balloon. *Id*., ¶¶ 37-46. The ReShape Balloon includes [redacted] through which fluid flows. SUF, ¶ 17; Bhoyrul Dec., ¶¶ 38-43. The fluid flows through the valves and into the two balloons of the ReShape Balloon. SUF, ¶¶ 18-20; Bhoyrul Dec. ¶¶ 40-44. Once the fluid flows through [redacted], it does not flow back out of the ReShape Balloon. SUF, ¶¶ 18-22; Bhoyrul Dec. ¶ 45. Following the filling of the balloons with fluid through the valves, a valve sealant is injected to seal the [redacted]. SUF, ¶ 22; Bhoyrul Dec. ¶ 44. This valve sealant further ensures that fluid cannot flow out of [redacted]. Bhoyrul Dec. ¶ 45.

A POSITA would understand [redacted], and fill tubes to constitute a valve system. The valve system is sealed with valve sealant, which can be considered part of the valve system. Bhoyrul Dec. ¶ 22. The valve system retains the fluid in the ReShape Balloon once the balloons of the device are inflated. *Id*. ¶ 23. Indeed, common sense requires such a function.

d. Third element.

The third element of claim 1 of the '930 patent recites: "the valve system comprises a respective valve structure for introducing fluid into each inflatable space-filling compartment of the plurality of inflatable space-filling compartments, wherein each respective valve structure includes at least a first valve in series with a second valve;" SUF, ¶ 8. A POSITA would understand the words of this claim limitation according to their plain and ordinary meaning without the need for further construction. Bhoyrul Dec., ¶ 48.

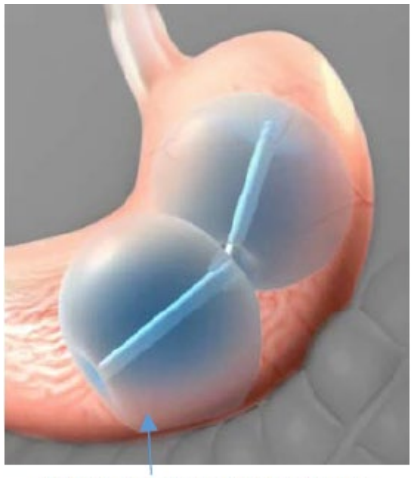
A POSITA would recognize this claim limitation as literally present in the ReShape Balloon. *Id.*, ¶¶ 47-49. The ReShape Balloon includes a valve structure [redacted] SUF, ¶ 82; Bhoyrul Dec. ¶ 49.

e. Fourth element.

The fourth element of claim 1 of the '930 patent recites: "wherein the obesity treatment device is to form, upon at least partially filling the plurality of inflatable space-filling compartments, to a curved shape conforming to a natural three-dimensional kidney shape of the stomach such that an outer surface of the obesity treatment device aligns against greater and lesser curvatures of the stomach." SUF, ¶ 8. A POSITA would understand the words of this claim limitation according to their plain and ordinary meaning without the need for further construction. Bhoyrul Dec., ¶ 51.

A POSITA would recognize this claim limitation as literally present in the ReShape Balloon. Bhoyrul Dec., ¶¶ 52-58. The ReShape Balloon is inflated after it is implanted into the patient's stomach. SUF, ¶ 14. When the device is inflated it takes a [redacted]

curved shape [redacted]. SUF, ¶ 14; Bhoyrul Dec., ¶¶ 53-57. When inflated, the ReShape Integrated Dual Balloon Assembly is designed to occupy a significant portion of the stomach while conforming to the natural shape and contour of the patient's stomach. SUF, ¶¶ 24-26, 49-57; Bhoyrul Dec. ¶¶ 53-57. The [redacted] SUF, ¶ 53; ¶¶ 49-59. Indeed, Defendants represented to their shareholders and the SEC that "we believe that our device differentiates itself with two interconnected balloons designed to better fit the natural contour of the stomach, thereby increasing the level of patient comfort." SUF, ¶ 57.



Inflated ReShape Dual Balloon

Fig. 2

The outer surface of the left side of the balloon aligns against the lesser curvature of the stomach and the outer surface of the right side of the balloon aligns against the greater curvature of the stomach as shown in the animation ReShape includes with its patient information guide. SUF, ¶ 37; Bhoyrul Dec., ¶¶ 54-57. This is consistent with a radiograph showing the device inside the patient's stomach. Bhoyrul Dec. ¶ 56.

In sum, the foregoing establishes by a preponderance of the evidence that each and every element of claim 1 of the '930 patent is literally present in the ReShape Balloon when that claim is properly understood according to its plain and ordinary meaning. No reasonable juror could find otherwise, and summary judgment of infringement as to claim 1 of the '930 patent is therefore appropriate.

2. Defendants infringe claim 1 of the '915 patent.

a. Preamble

The preamble of claim 1 of the '915 patent recites: "A gastric balloon

structure for deploying in a gastric cavity of a patient, comprising." SUF, ¶ 9. To the extent the preamble is limiting, it is met because the ReShape Balloon is a gastric balloon structure that is deployed in a gastric cavity of a patient. SUF, ¶ 28; Bhoyrul Dec., ¶¶ 59-60.

b. First element

The first element of claim 1 of the '915 patent recites: "at least two isolated non-concentric inflatable chambers, wherein each chamber of the at least two isolated non-concentric inflatable chambers has a respective inflated state volume such that deflation of any single chamber of the at least two isolated non-concentric inflatable chambers leaves the inflated state volume of the remaining chambers of the at least two isolated non-concentric inflatable chambers unaffected;" A POSITA would understand the words of this claim limitation according to their plain and ordinary meaning without the need for further construction. Bhoyrul Dec., ¶ 62.

A POSITA would recognize this claim limitation as literally present in the ReShape Balloon. Bhoyrul Dec., ¶¶ 63-66. The balloons of the ReShape Balloon are inflatable chambers. SUF, ¶ 29; Bhoyrul Dec., ¶ 64. Each balloon has its own specific inflated state volume. SUF, ¶ 15. The balloons are non-concentric at least because they do not share a common center and would not fit within each other. SUF, ¶ 30; Bhoyrul Dec., ¶ 66. The balloons of the ReShape Balloon are not in fluid communication with each other. Bhoyrul Dec., ¶¶ 63-65. Accordingly, if one deflates, the other will remain inflated. SUF, ¶ 31; Bhoyrul Dec., ¶¶ 64-65.

c. Second element

The second element of claim 1 of '915 patent recites "a valve system for introducing a fluid into the at least two isolated non-concentric inflatable chambers and for retaining upon inflation, the fluid in the at least two isolated non-concentric inflatable chambers;" SUF, ¶ 9. A POSITA would understand the words of this

claim limitation according to their plain and ordinary meaning without the need for further construction. Bhoyrul Dec., ¶ 68.

A POSITA would recognize this claim limitation as literally present in the ReShape Balloon. Bhoyrul Dec., ¶¶ 69-76. The ReShape Balloon includes [redacted]. SUF, ¶ 17; Bhoyrul Dec., ¶¶ 69-73. The fluid flows through the valves and into the two balloons of the ReShape Balloon. SUF, ¶¶ 18-20; Bhoyrul Dec. ¶¶ 73-75. Once the fluid flows through [redacted], it does not flow back out of the ReShape Balloon. SUF, ¶¶ 18-22; Bhoyrul Dec. ¶¶ 71-76. Following the filling of the balloons with fluid through the valves, a valve sealant is injected to seal [redacted]. SUF, ¶ 22; Bhoyrul Dec. ¶ 76. This valve sealant further ensures that fluid cannot flow out of [redacted] once fluid flows through it. Bhoyrul Dec. ¶ 76.

A POSITA would understand the [redacted], and fill tubes to constitute a valve system. Bhoyrul Dec. ¶ 75. The valve system is sealed with valve sealant, which can be considered part of the valve system. *Id*.¶ 76. The valve system retains the fluid in the ReShape Balloon once the balloons of the device are inflated. *Id*. ¶¶ 75-76.

d. Third element

The third limitation of claim 1 '915 patent recites "a flexible central spine spanning a gap between and fixedly attached to both a first chamber of the at least two isolated non-concentric inflatable chambers and a second chamber of the at least two isolated non-concentric inflatable chambers." SUF, ¶ 9. A POSITA would understand the words of this claim limitation according to their plain and ordinary meaning without the need for further construction. Bhoyrul Dec., ¶ 78.

A POSITA would recognize this claim limitation as literally present in the ReShape Balloon. Bhoyrul Dec., ¶¶ 79-82. The ReShape Balloon includes a "central silicone shaft" that is attached to the balloons and spans a gap between the two balloons. SUF, ¶ 32; Bhoyrul Dec. ¶¶ 80-81. The central silicone shaft is flexible. *Id.*; *id.* The flexible central silicone shaft runs through the length of the balloon device acting as a spine. SUF, ¶ 35; Bhoyrul Dec. ¶¶ 80-81. The central silicone shaft connects the two balloons in the ReShape Balloon. SUF, ¶ 33; Bhoyrul Dec. ¶¶ 80-81. The above-picture from Defendants' response to Interrogatory No. 5 [redacted] Alciati Decl., Ex. 34 at 7.

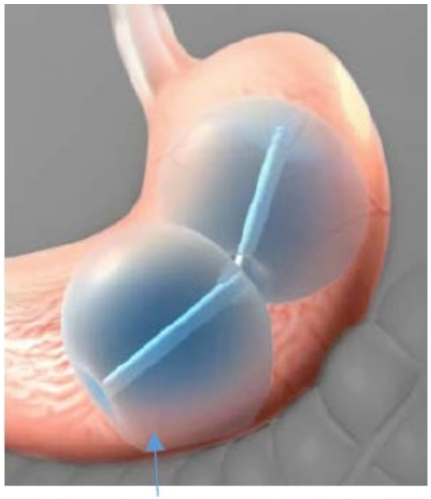
A POSITA would understand the "central silicone shaft" of the ReShape Balloon to be a flexible central spine that is attached to the two balloons and that spans a gap between the two balloons. Bhoyrul Dec., ¶¶ 79-81.

e. Fourth element

The fourth limitation of claim 1 '915 patent recites "wherein the gastric balloon structure, in its inflated state, assumes a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity, such that the flexible central spine flexibly conforms, upon at least partially filling the at least two isolated non-concentric inflatable chambers, the gastric balloon structure of the natural three-dimensional kidney shape of the gastric cavity." SUF, ¶ 9. A POSITA would understand the words of this claim limitation according to their plain and ordinary meaning without the need for further construction. Bhoyrul Dec., ¶ 84.

A POSITA would recognize this claim limitation as literally present in the ReShape Balloon. Bhoyrul Dec., ¶¶ 85-87. The ReShape Balloon is inflated after

it is implanted into the patient's stomach. SUF, ¶ 14. When the device is inflated it takes a curved shape as shown in the figure to the right. SUF, ¶ 14; Bhoyrul Dec., ¶¶ 51-57; 87. When inflated, the ReShape Integrated Dual Balloon Assembly is designed to occupy a significant portion of the stomach while conforming to the natural shape and contour of the patient's stomach. SUF, ¶¶ 24-26; Bhoyrul Dec. ¶¶ 51-57; 87. As the image on the right shows, the flexible central spine of the ReShape device bends and conforms the device to the shape of the patient's stomach. SUF, ¶¶ 37-38, 49-59; Bhoyrul Dec. ¶ 86. In fact, ReShape has represented that ReShape Balloon is [redacted] SUF, ¶ 55.



Inflated ReShape Dual Balloon

Fig. 2

f. Fifth element.

The fifth element of claim 1 of the '915 patent recites "wherein a respective fluid volume for filling each chamber of the at least two isolated non-concentric inflatable chambers is selected based upon dimensions of the gastric cavity of the patient." SUF, ¶ 9. A POSITA would understand the words of this claim limitation according to their plain and ordinary meaning without the need for further construction. Bhoyrul Dec., ¶ 89.

A POSITA would recognize this claim limitation as literally present in the

ReShape Balloon. Bhoyrul Dec., ¶¶ 89-94. The inflation volume for the balloons is determined, in part, based on the stature of the patients. SUF, ¶ 39; Bhoyrul Dec., ¶ 88. For patients over 64.5 inches in height, a fill volume of 450cc per balloon is recommended. SUF, ¶ 41; Bhoyrul Dec., ¶ 91. For patients under 64.5 inches in height, a fill volume of 375cc is recommended. SUF, ¶ 42; Bhoyrul Dec., ¶ 91. Dr. Bhoyrul explains that "the dimensions of the patient's stomach will, in part, depend on the patient's stature." Bhoyrul Dec., ¶ 92. A skilled artisan would thus understand that the fill volume of the balloons of the ReShape Balloon is based on the size of the patient's stomach. *Id*.

Additionally, the filling process of the balloons of the ReShape Balloon is monitored through endoscopic visualization. SUF, ¶ 43; Bhoyrul Dec., ¶ 93-94. This visualization allows the physician to determine whether the patient's anatomy can accommodate the minimal fill level of 375cc balloons. Bhoyrul Dec., ¶ 93-94. If the physician determines that not be the case through the endoscopic visualization, the place procedure is discontinued. *Id*. ¶ 94. This is yet another way in which the fill volume is based on the dimensions of the patient's gastric cavity. *Id*.

In sum, the foregoing establishes by a preponderance of the evidence that each and every element of claim 1 of the '915 patent is literally present in the ReShape Balloon when that claim is properly understood according to its plain and ordinary meaning. No reasonable juror could find otherwise, and summary judgment of infringement as to claim 1 of the '915 patent is therefore appropriate.

3. Defendants infringe claim 1 of the '367 patent.

a. Preamble

The preamble of claim 1 of the '367 patent "A free floating, untethered gastric balloon structure for deploying in a gastric cavity of a patient, comprising." SUF, ¶ 10. To the extent the preamble is limiting, it is met because the ReShape

Balloon is a free-floating, untethered gastric balloon structure that is deployed in a gastric cavity of a patient. SUF, ¶¶ 44-45; Bhoyrul Dec., ¶¶ 95-98.

b. First element

The first element of claim 1 of the '367 patent recites "at least two isolated non-concentric inflatable chambers, wherein each chamber of the at least two isolated non-concentric inflatable chambers has a respective inflated state volume such that deflation of any single chamber of the at least two isolated non-concentric inflatable chambers leaves the inflated state volume of the remaining chambers of the at least two isolated non-concentric inflatable chambers unaffected." SUF, ¶ 10. A POSITA would understand the words of this claim limitation according to their plain and ordinary meaning without the need for further construction. Bhoyrul Dec., ¶ 100.

A POSITA would recognize this claim limitation as literally present in the ReShape Balloon. Bhoyrul Dec., ¶¶ 101-105. A POSITA would understand the two balloons of the ReShape Balloon to be inflatable chambers. SUF, ¶ 29; Bhoyrul Dec., ¶ 64. The balloons are non-concentric at least because they do not share a common center and would not fit within each other. SUF, ¶ 30; Bhoyrul Dec., ¶ 104. The balloons of the ReShape Balloon are not in fluid communication with each other. Bhoyrul Dec., ¶¶ 102-103. Accordingly, if one deflates, the other will remain inflated. SUF, ¶ 31; Bhoyrul Dec., ¶ 105.

c. Second element

The second limitation of the claim 1 of the '367 patent recites "a valve system for introducing a fluid into the at least two isolated non-concentric inflatable chambers and for retaining, upon inflation, fluid in the at least two isolated non-concentric inflatable chambers." SUF, ¶ 10. A POSITA would understand the words of this claim limitation according to their plain and ordinary meaning without the need for further construction. Bhoyrul Dec., ¶ 107.

A POSITA would recognize this claim limitation as literally present in the ReShape Balloon. Bhoyrul Dec., ¶¶ 107-115. The ReShape Balloon includes [redacted] valves through which fluid flows. SUF, ¶ 17; Bhoyrul Dec., ¶¶ 109-112. The fluid flows through the valves and into the two balloons of the ReShape Balloon. SUF, ¶¶ 18-20; Bhoyrul Dec. ¶ 112-115. Once the fluid flows through [redacted], it does not flow back out of the ReShape Balloon. SUF, ¶¶ 18-22; Bhoyrul Dec. ¶¶ 112-113. Following the filling of the balloons with fluid through the valves, a valve sealant is injected to seal [redacted]. SUF, ¶ 22; Bhoyrul Dec. ¶ 114. This valve sealant further ensures that fluid cannot flow out of the flapper valve once fluid flows through it. Bhoyrul Dec. ¶ 114.

A POSITA would understand [redacted], and fill tubes to constitute a valve system. *Id*. The valve system is sealed with valve sealant, which can be considered part of the valve system. *Id*. The valve system retains the fluid in the ReShape Balloon once the balloons of the device are inflated. *Id*. ¶ 115.

d. Third element

The third element of claim 1 of the '367 patent recites "a flexible member spanning a gap between and fixedly attached to both a first chamber of the at least two isolated non-concentric inflatable chambers and a second chamber of the at least two isolated non-concentric inflatable chambers, said flexible member carrying inflation tubes that are in fluid communication with the at least two isolated non-concentric inflatable chambers." SUF, ¶ 10. A POSITA would understand the words of this claim limitation according to their plain and ordinary meaning without the need for further construction. Bhoyrul Dec., ¶ 117.

A POSITA would recognize this claim limitation as literally present in the ReShape Balloon. Bhoyrul Dec., ¶¶ 118-125. The ReShape Balloon includes a

"central silicone shaft" that is attached to the balloons and spans a gap between the two balloons. SUF, ¶ 32; Bhoyrul Dec., ¶¶ 119-120. The central silicone shaft is flexible. *Id*.; *id*. The flexible central silicone shaft runs through the length of the balloon device acting as a spine. SUF, ¶ 35; Bhoyrul Dec., ¶ 120. The central silicone shaft connects the two balloons in the ReShape Balloon. SUF, ¶ 33; Bhoyrul Dec. ¶ 120.

The central silicone shaft of the ReShape balloon [redacted]. SUF, ¶ 46, Bhoyrul Dec., ¶¶ 122-125. The [redacted] are used to fill fluid into the balloons of the ReShape Balloon. SUF, ¶ 47; Bhoyrul Dec., ¶¶ 122-125.

e. Fourth element

The fourth limitation of claim 1 of the '367 patent recites "wherein the gastric balloon structure is configured to float freely in the patient's gastric cavity and is not connected to any catheter, lumen or tether after deployment in the patient's gastric cavity;" SUF, ¶ 10. A POSITA would understand the words of this claim limitation according to their plain and ordinary meaning without the need for further construction. Bhoyrul Dec., ¶ 127.

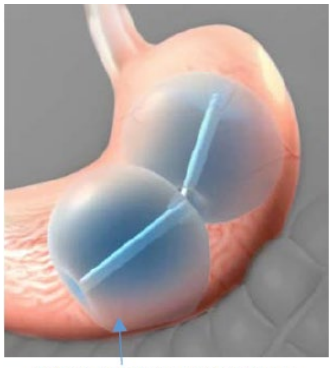
A POSITA would recognize this claim limitation as literally present in the ReShape Balloon. Bhoyrul Dec., ¶¶ 128-129. The ReShape Balloon is a free-floating, untethered gastric balloon structure that is deployed in a gastric cavity of a patient and is not connected to any catheter, lumen, or tether after deployment. SUF, ¶¶ 44-45; Bhoyrul Dec., ¶¶ 128-129.

f. Fifth element

The fifth element of claim 1 of the '367 patent recites "wherein the gastric balloon structure, in its inflated state, assumes a curved shape conforming to a natural three-dimensional kidney shape of the gastric cavity, such that the flexible

member flexibly conforms, upon at least partially filling the at least two isolated non-concentric inflatable chambers, the gastric balloon structure to the natural three-dimensional kidney shape of the gastric cavity." A POSITA would understand the words of this claim limitation according to their plain and ordinary meaning without the need for further construction. Bhoyrul Dec., ¶ 131.

A POSITA would recognize this claim [redacted] ReShape Balloon is inflated after it is implanted into the patient's stomach. SUF, ¶ 14. When the device is inflated it takes a curved shape as shown in the figure to the right. SUF, ¶ 14; Bhoyrul Dec., ¶¶ 129-131. When inflated, the ReShape Integrated Dual Balloon Assembly is designed to occupy a significant portion of the stomach while conforming to the natural shape and contour of the patient's stomach. SUF, ¶¶ 24-26; ¶¶ 49-59; Bhoyrul Dec. ¶¶ 132-134. As the image on the right shows, the flexible central spine of the ReShape device bends and conforms the device to the shape of the patient's stomach. SUF, ¶¶ 37-38; Bhoyrul Dec., ¶¶ 132-134. In fact, ReShape has represented that ReShape Balloon is [redacted] SUF, ¶ 55.



Inflated ReShape Dual Balloon

Fig. 2

In sum, the foregoing establishes by a preponderance of the evidence that each and every element of claim 1 of the '367 patent is literally present in the ReShape Balloon when that claim is properly understood according to its plain and

ordinary meaning. No reasonable juror could find otherwise, and summary judgment of infringement as to claim 1 of the '367 patent is therefore appropriate.

C. Defendants infringe dependent claims reciting that the same type of fluid is used to fill the compartments or chambers.

Dependent claim 11 of the '930 patent, dependent claim 7 of the '367 patent both depend from claim 1 of those patents (discussed above) and recite that the space-filling compartments or inflatable chambers are filled with the same fluid. SUF, ¶¶ 83, 84 The balloons of the ReShape Balloon are filled with the same fluid, i.e. saline. SUF, ¶ 85. Accordingly, the ReShape Balloon infringes dependent claim 11 of the '930 patent, dependent claim 7 of the '367 patent.

D. Defendants infringe claims 5 and 6 of the '930 patent.

Claim 5 depends from claim 1 and recites "wherein an outer surface of each of the inflatable space-filling compartments aligns against greater and lesser curvatures of the stomach." The outer surface of the left side of the balloon aligns against the lesser curvature of the stomach and the outer surface of the right side of the balloon aligns against the greater curvature of the stomach. SUF, ¶ 37; Bhoyrul Dec., ¶¶ 54-57. Accordingly, Defendants infringe claim 5 of the '930 patent

Claim 6 depends from claim 5 and recites "the obesity treatment device of claim 5, wherein the obesity treatment device is untethered in the stomach after inflation." The ReShape Balloon is a free-floating, untethered gastric balloon structure that deployed in a gastric cavity of a patient unconnected to any catheter, lumen, or tether after deployment. SUF, ¶¶ 44-45; Bhoyrul Dec., ¶¶ 128-129.

CONCLUSION

For the foregoing reasons, Fulfillium respectfully requests that the Court grant its motion and enter an order awarding partial summary judgment of infringement.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of this document has been served on all parties through counsel of record on July 9, 2019 via the Court's CM/ECF system.

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